

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In re: LANTUS DIRECT PURCHASER
ANTITRUST LITIGATION

Civil Action No. 1:16-cv-12652-LTS-JCB

Leave to File Under Seal Granted
Feb. 28, 2025, Docket No. 566

**DECLARATION OF KRISTEN A. JOHNSON IN SUPPORT OF
PURCHASERS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND
MOTIONS TO EXCLUDE TESTIMONY OF SANOFI'S EXPERTS**

I, Kristen A. Johnson, hereby declare as follows:

I am a member of the bar of the Supreme Judicial Court of the Commonwealth of Massachusetts and of the United States District Court for the District of Massachusetts, and United States Court of Appeals for the First Circuit. I am a partner in the Boston office of Hagens Berman Sobol Shapiro LLP, and counsel for Plaintiffs FWK Holdings, LLC; Meijer, Inc.; Meijer Distribution, Inc.; AmerisourceBergen Corporation; AmerisourceBergen Drug Corporation; H.D. Smith, LLC; Valley Wholesale Drug Company, LLC; Smith Medical Partners, LLC; ASD Specialty Healthcare, Inc.; JM Blanco; Cardinal Health, Inc.; The Harvard Drug Group, L.L.C.; and McKesson Corporation. If called to testify as to the matters set forth herein, I would do so based upon my personal knowledge and am competent to testify to the matters herein.

I make this declaration in support of Purchasers' Motion for Partial Summary Judgment, Purchasers' Motion to Exclude the Testimony of Sanofi's Experts Gregory Glover, Roger Williams, and Nicholas Godici, and Purchasers' Motion to Partially Exclude Opinions of Sanofi's Experts Nicholas C. Davies and Mark Robbins.

1. Attached as **PX-1** is a true and accurate copy of Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872 (July 10, 1989) (“Proposed Rules (1989)”).
2. Attached as **PX-2** is a true and accurate copy of Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338 (October 3, 1994) (“Final Rules (1994)”).
3. Attached as **PX-3** is a certified copy of U.S. Patent No. 5,656,722 (“722 patent”).
4. Attached as **PX-4** is a true and accurate copy of an April 20, 2000 FDA letter to Aventis Pharmaceuticals Inc. approving Aventis NDA 21-081 (Lantus), SANOFI_01339785 – SANOFI_01339787 (“Apr. 20, 2000 Lantus approval ltr.”).
5. Attached as **PX-5** is a true and accurate copy of Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed, 67 Fed. Reg. 65,448, 65,448 (Oct. 24, 2002) (“Proposed Rules (2002)”).
6. Attached as **PX-6** is a true and accurate copy of Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed; Final Rule, 68 Fed. Reg. 36,676 (June 18, 2003) (“2003 Final Rule”).
7. Attached as **PX-7** is a true and accurate copy of an October 2004 FDA draft Guidance for Industry, Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003, Questions and Answers (“Oct. 2004 FDA Guidance”).

8. Attached as **PX-8** is a true and accurate copy of an April 25, 2007 FDA Approval Package for NDA 21-081/S-024, Exhibit Schultz 6 from the deposition of William Schultz (“Apr. 25, 2007 Lantus SoloStar approval package”).

9. Attached as **PX-9** is a true and accurate copy of 21 C.F.R. § 314.50 (2008).

10. Attached as **PX-10** is a true and accurate copy of 21 C.F.R. § 314.430 (2008).

11. **PX-11** has been intentionally omitted.

12. Attached as **PX-12** is a true and accurate copy of a Feb. 10, 2009 corrected Form 3542 for U.S. Patent No. 5,656,722 and Form 3542 for U.S. Patent No. 7,476,652, Bates numbered SAMA03617310 – SAMA0361317, PX0075A to the deposition of Nicholas Poulos (“Form 3542 for ’722 patent”).

13. Attached as **PX-13** is a true and accurate copy of 21 U.S.C. § 355 (2010).

14. Attached as **PX-14** is a true and accurate copy of 21 C.F.R. § 314.3 (2010).

15. Attached as **PX-15** is a true and accurate copy of the February 11, 2011 Answer, Affirmative Defenses, and Counterclaims of defendant Intelliject in *King Pharmaceuticals, Inc. and Meridien Technologies, Inc. v. Intelliject, Inc.*, No. 11-065 (BMS) (Feb. 11, 2011 D. Del.), Docket No. 11, PX0206 to the deposition of David Frischkorn.

16. Attached as **PX-16** is a true and accurate copy of 21 C.F.R. § 314.53 (2011).

17. Attached as **PX-17** is a certified copy of U.S. Patent No. 7,918,833 (“’833 patent”).

18. Attached as **PX-18** is a true and accurate copy of a May 4, 2011 Form 3542 for U.S. Patent No. 7,918,833, Bates numbered SAMA03593901 – SAMA03593905, PX0075D to the deposition of Nicholas Poulos (“May 4, 2011 Form 3542 for the ’833 patent”).

19. Attached as **PX-19** is a true and accurate copy of a [REDACTED]
[REDACTED], Bates numbered MERCK-AT-0003091 –
MERCK-AT-0003103 [REDACTED]

20. Attached as **PX-20** is a true and accurate copy of excerpts from the 2014 FDA Approved Drug Products with Therapeutic Equivalence Evaluations, 34th edition (2014), Bates numbered SAMA04305176 – SAMA04305203, SAMA04305396 & SAMA04306227 (“2014 Orange Book excerpts”).

21. Attached as **PX-21** is a true and accurate copy of a February 6-7, 2013 Merck
[REDACTED], Bates numbered MERCK-AT-0404754 – MERCK-AT-0404772 [REDACTED]
[REDACTED]

22. Attached as **PX-22** is a true and accurate copy of a February 18, 2013 Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd. and Merck Sharp & Dohme Corp. (“Feb. 18, 2013 Samsung/Merck agreement.”).

23. Attached as **PX-23** is a true and accurate copy of excerpts from the August 2013 FDA Cumulative Supplement 8, Approved Drug Products with Therapeutic Equivalence Evaluations, Bates numbered SAMA04304476 – SAMA04304485 & SAMA04304584 (“Aug. 2013 Patent and Exclusivity Drug List – Cumulative Supplement 08”).

24. Attached as **PX-24** is a certified copy of U.S. Patent No. 8,512,297 (“297 patent”).

25. Attached as **PX-25** is a true and accurate copy of an August 21, 2013 Form 3542 for U.S. Patent No. 8,512,297, Bates numbered SAMA03516768 – SAMA0351672, PX0075E to the deposition of Nicholas Poulos (“Aug. 21, 2013 Form 3542 for ’297 patent”).

26. Attached as **PX-26** is a true and accurate copy of an October 14, 2013 Eli Lilly and Company paragraph III and paragraph IV certifications, Bates numbered EL-FWK-045454–58, Ex. Schultz 9 from the deposition of William Schultz (“Oct. 14, 2013 para. III and IV cert.”).

27. Attached as **PX-27** is a certified copy of U.S. Patent No. 8,556,864 (“’864 patent”).

28. Attached as **PX-28** is a true and accurate copy of an October 17, 2013 Eli Lilly and Company FDA Form 356h for NDA 205692, insulin glargine, for Abrasia KwikPen, Bates numbered EL-FWK-044942 – EL-FWK-044944 (“Oct. 17, 2013 Form FDA 356h for Lilly’s NDA 205692”).

29. Attached as **PX-29** is a true and accurate copy of an October 17, 2013 Eli Lilly and Company submission letter for NDA 205692, ABASRIA KwikPen, Bates numbered EL-FWK-044981 – EL-FWK-044983, Ex. Schultz 8 from the deposition of William Schultz (“Oct. 17, 2013 Lilly NDA 205692 submission ltr.”).

30. Attached as **PX-30** is a true and accurate copy of an October 17, 2013 Note to Reviewers included in Eli Lilly and Company’s submission of NDA 205692, Bates Numbered EL-FWK-045448 – EL-FWK-045453 (“October 17, 2013 Note to Reviewers”).

31. Attached as **PX-31** is a true and accurate copy of an October 25, 2013 Form 3542 for U.S. Patent No. 8,556,864, Bates numbered SAMA03587437 – SAMA03587441, PX0075F to the deposition of Nicholas Poulos (“Oct. 25, 2013 Form 3542 for ’864 patent”).

32. Attached as **PX-32** is a true and accurate copy of a December 6, 2013 Eli Lilly and Company paragraph IV certification for U.S. Patent No. 8,556,864, Bates numbered EL-FWK-045587 (“Dec. 6, 2013 Lilly paragraph IV cert.”).

33. Attached as **PX-33** is a true and accurate copy of a December 9, 2013 Eli Lilly and Company cover letter for paragraph IV certification, Bates numbered EL-FWK-045586 (“Dec. 9, 2013 Lilly patent cert. ltr.”).

34. Attached as **PX-34** is a certified copy of U.S. Patent No. 8,603,044 (“’044 patent”).

35. Attached as **PX-35** is a true and accurate copy of a Dec. 18, 2013 Eli Lilly and Company letter to Sanofi regarding notice of paragraph IV certifications concerning NDA 205692, Bates numbered SAMA03449750 – SAMA03449791 (“Dec. 18, 2013 Lilly notice of paragraph IV cert.”).

36. Attached as **PX-36** is a true and accurate copy of a January 6, 2014 Form 3542 for U.S. Patent No. 8,603,044, Bates numbered SAMA03519870 – SAMA03519874, PX0075G to the deposition of Nicholas Poulos (“Jan. 6, 2014 Form 3542 for ’044 patent”).

37. Attached as **PX-37** is a true and accurate copy of a January 9, 2014 Eli Lilly and Company revised paragraph III certification for U.S. Patent No. 5,656,722, Bates numbered EL-FWK-045822 (“Jan. 9, 2014 Lilly revised para. III cert.”).

38. Attached as **PX-38** is a true and accurate copy of a January 23, 2014 FDA letter to Eli Lilly and Company [REDACTED] Bates numbered EL-FWK-060086 – EL-FWK-060087 (“Jan. 23, 2014 FDA ltr. [REDACTED]”).

39. Attached as **PX-39** is a true and accurate copy of a January 23, 2014 Eli Lilly and Company letter to Sanofi regarding notice of amended paragraph IV certifications, Bates

numbered SAMA03515447 – SAMA03515495 (“Jan. 23, 2014 Lilly amended notice of para. IV certs.”).

40. Attached as **PX-40** is a true and accurate copy of a January 30, 2014 Complaint in *Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GMBH v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.), Bates numbered SAMA03594234 – SAMA03594243 (“Jan. 30, 2014 *Sanofi v. Lilly* Compl.”).

41. Attached as **PX-41** is a true and accurate copy of a February 19, 2014 Eli Lilly and Company Answer and Counterclaims in *Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GMBH v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.), Docket No. 8, Bates numbered SAMA00004411 – SAMA00004510, at Counterclaim Counts I, II and V (“Lilly Answer & Countercl.”).

42. Attached as **PX-42** is a true and accurate copy of a March 25, 2014 Form 3542 for U.S. Patent No. 8,679,069, Bates numbered SAMA03398785 – SAMA03398780, PX0075H to the depositon of Nicholas Poulos (“Mar. 25, 2014 Form 3542 for ’069 patent”).

43. Attached as **PX-43** is a certified copy of U.S. Patent No. 8,679,069 (“’069 patent”).

44. Attached as **PX-44** is a true and accurate copy of an April 23, 2014 [REDACTED], Bates numbered MERCK-AT-0002974 – MERCK-AT-0003009 [REDACTED].

45. Attached as **PX-45** is a certified copy of U.S. Patent No. 8,992,486 (“’486 patent”).

46. Attached as **PX-46** is a true and accurate copy of an April 6, 2015 Form 3542 for U.S. Patent No. 8,992,486, Bates numbered SAMA03594883 – SAMA03594887, PX0075I to the deposition of Nicholas Poulos (“Apr. 6, 2015 Form 3542 for ’486 patent”).

47. Attached as **PX-47** is a certified copy of U.S. Patent No. 9,011,391 (“’391 patent”).

48. Attached as **PX-48** is a true and accurate copy of an April 29, 2015 Form 3542 for U.S. Patent No. 9,011,391, Bates numbered SAMA03522781 – SAMA0352785, PX0075J to the deposition of Nicholas Poulos (“Apr. 29, 2015 Form 3542 for ’391 patent”).

49. Attached as **PX-49** is a true and accurate copy of a January 11, 2016 Form 3542 for U.S. Patent No. 9,233,211, Bates numbered SAMA03528647 – SAMA03528650, PX0075K to the deposition of Nicholas Poulos (“Jan. 11, 2016 Form 3542 for ’211 patent”).

50. Attached as **PX-50** is a certified copy of U.S. Patent No. 9,233,211 (“’211 patent”).

51. Attached as **PX-51** is a true and accurate copy of an April 25, 2016 corrected Form 3542 for U.S. Patent No. 9,011,391, Bates numbered SAMA03529338 – SAMA03529343, PX0075J to the deposition of Nicholas Poulos (“Apr. 25, 2016 corrected Form 3542 for ’391 patent”).

52. Attached as **PX-52** is a true and accurate copy of a May 30, 2016 Merck Sharp & Dohme Corp. Form 356h for NDA 208722 (insulin glargine), Bates numbered MERCK-AT-0003030 – MERCK-AT-0003038 (“May 30, 2016 FDA Form 356h for Merck’s NDA 208722”).

53. Attached as **PX-53** is a true and accurate copy of a May 30, 2016 submission letter for Merck NDA 208722, Bates numbered MERCK-AT-0022195 – MERCK-AT-0022198 (“May 30, 2016 Merck insulin glargine pen NDA”).

54. Attached as **PX-54** is a true and accurate copy of a May 30, 2016 excerpt (Module 3.2.P.1) from Merck NDA 208722, Bates Numbered MERCK-AT-0023320 – MERCK-AT-0023323 (“May 30, 2016 Merck NDA excerpt”).

55. Attached as **PX-55** is a true and accurate copy of a June 2016 [REDACTED], Bates numbered MERCK-AT-0002799 – MERCK-AT-0002941 [REDACTED].

56. Attached as **PX-56** is a true and accurate copy of an August 4, 2016 letter from Gregory Bonifield (Quinn Emanuel) on behalf of Merck Sharp & Dohme Corp. re: notice of certification under 21 U.S.C. § 355(b)(2)(A)(iv) and 21 C.F.R. § 314.52 concerning U.S. Patent Nos. 7,476,652, 7,713,930, 7,918,833, 8,512,297, 8,556,864, 8,603,044, 8,679,069, 8,992,486, 9,011,391, & 9,233,211, Bates numbered SAMA03785697 – SAMA03785761 (“Aug. 4, 2016 Merck notice of paragraph IV cert.”).

57. Attached as **PX-57** is a true and accurate copy of an August 8, 2016 email from Kathrin Koerner to Stephanie Donahue attaching Merck paragraph IV notice, Bates numbered SAMA03785696 (“Aug. 8, 2016 cover email for Merck paragraph IV cert.”).

58. Attached as **PX-58** is a certified copy of U.S. Patent No. 9,408,979 (“‘979 patent”).

59. Attached as **PX-59** is a true and accurate copy of the August 31, 2016 letter from Catherine L. Kohler, Merck’s Director of Global Regulatory Affairs to FDA re delivery of paragraph IV notice to NDA holder and patents record owner, Bates numbered MERCK-AT-0166978 – MERCK-AT-0166979 (“Aug. 31, 2016 Merck paragraph IV delivery receipt”).

60. Attached as **PX-60** is a true and accurate copy of a September 15, 2016 Form 3542 for U.S. Patent No. 9,408,979, Bates numbered SAMA03827092 – SAMA03827096, PX0075L to the deposition of Nicholas Poulos (“Sept. 15, 2016 Form 3542 for ’979 patent.”)

61. Attached as **PX-61** is a true and accurate copy of a September 16, 2016 Complaint in *Sanofi Aventis U.S. LLC, et al. v. Merck Sharp & Dohme Corp.*, No. 16-cv-00812 (D. Del.), Bates numbered SAMA03631393 – SAMA03631561 (“Sept. 16, 2016 *Sanofi v. Merck* Compl.”).

62. Attached as **PX-62** is a certified copy of U.S. Patent No. 9,526,844 (“’844 patent”).

63. Attached as **PX-63** is a true and accurate copy of a December 27, 2016 Form 3542 for U.S. Patent No. 9,526,844, Bates numbered SAMA03532659 – SAMA03532664, PX0075M to the deposition of Nicholas Poulos (“Dec. 27, 2016 Form 3542 for ’844 patent”).

64. Attached as **PX-64** is a true and accurate copy of a January 3, 2017 Form 3542 for U.S. Patent No. 9,533,105, Bates numbered SAMA03458382 – SAMA03458387, PX0075N to the deposition of Nicholas Poulos (“Jan. 3, 2017 Form 3542 for ’105 patent”).

65. Attached as **PX-65** is a certified copy of U.S. Patent No. 9,533,105 (“’105 patent”).

66. Attached as **PX-66** is a certified copy of U.S. Patent No. 9,561,331 (“’331 patent”).

67. Attached as **PX-67** is a true and accurate copy of a February 7, 2017 Form 3542 for U.S. Patent No. 9,561,331, Bates numbered SAMA03829177 – SAMA03829182, PX0075O to the deposition of Nicholas Poulos (“Feb. 7, 2017 Form 3542 for ’331 patent”).

68. Attached as **PX-68** is a true and accurate copy of a March 28, 2017 Form 3542 for U.S. Patent Nos. 9,604,008 and 9,604,009, Bates numbered SAMA035458466 – SAMA035458476, PX0075P to the deposition of Nicholas Poulos (“Mar. 28, 2017 Form 3542 for ‘008 and ‘009 patents”).

69. Attached as **PX-69** is a certified copy of U.S. Patent No. 9,604,008 (“‘008 patent”).

70. Attached as **PX-70** is a certified copy of U.S. Patent No. 9,604,009 (“‘009 patent”).

71. Attached as **PX-71** is a true and accurate copy of 21 C.F.R. § 314.125 (2017).

72. Attached as **PX-72** is a true and accurate copy of an April 4, 2017 Form 3542 for U.S. Patent No. 9,610,409, Bates numbered SAMA03458558 – SAMA03458563, PX0075Q to the deposition of Nicholas Poulos (“Apr. 4, 2017 Form 3542 for ‘409 patent”).

73. Attached as **PX-73** is a certified copy of U.S. Patent No. 9,610,409 (“‘409 patent”).

74. Attached as **PX-74** is a true and accurate copy of an April 18, 2017 Form 3542 for U.S. Patent No. 9,623,189, Bates numbered SAMA03458657 – SAMA03458662, PX0075R to the deposition of Nicholas Poulos (“Apr. 18, 2017 Form 3542 for ‘189 patent”).

75. Attached as **PX-75** is a certified copy of U.S. Patent No. 9,623,189 (“‘189 patent”).

76. Attached as **PX-76** is a true and accurate copy of an April 24, 2017 letter from Merck to FDA re insulin glargine vial NDA, Bates number MERCK-AT-0001008 – MERCK-AT-0001011 (“Apr. 24, 2017 Merck insulin glargine vial NDA”).

77. Attached as **PX-77** is a true and accurate copy of a July 19, 2017 letter from FDA providing Tentative Approval of Merck NDA 208722, Bates numbered MERCK-AT-0000021 – MERCK-AT-0000065, Dep. Ex. 16 to deposition of Janie Wang (“July 19, 2017 tentative approval ltr. for Merck NDA 208722”).

78. Attached as **PX-78** is a certified copy of U.S. Patent No. 9,717,852 (“’852 patent”).

79. Attached as **PX-79** is a certified copy of U.S. Patent No. 9,775,954 (“’954 patent”).

80. Attached as **PX-80** is a true and accurate copy of an October 3, 2017 Form 3542 for U.S. Patent No. 9,775,954, Bates numbered SAMA03829624 – SAMA03829628, PX0075S to the deposition of Nicholas Poulos (“Oct. 3, 2017 Form 3542 for ’954 patent”).

81. Attached as **PX-81** is a true and accurate copy of an October 10, 2017 document titled “[REDACTED] Bates numbered MERCK-AT-0000856 – MERCK-AT- 0000879, Exhibit 0020 from the deposition of Janie Wang ([REDACTED]).

82. Attached as **PX-82** is a certified copy of U.S. Patent No. 9,827,379 (“’379 patent”).

83. Attached as **PX-83** is a true and accurate copy of a November 29, 2017 Form 3542 for U.S. Patent No. 9,827,379, Bates numbered SAMA03459072 – SAMA03459076, PX0075T to the deposition of Nicholas Poulos (“Nov. 29, 2017 Form 3542 for ’379 patent”).

84. Attached as **PX-84** is a true and accurate copy of a January 30, 2018 email [REDACTED], Bates numbered MERCK-AT-0404784 (“Jan. 30, 2018 Merck email”).

85. Attached as **PX-85** is a true and accurate copy of a March 2018 presentation [REDACTED]
[REDACTED] Bates
numbered MERCK-AT-0404796 – MERCK-AT-0404823, Exhibit 0014 from the deposition of
Janie Wang (“[REDACTED]”).

86. Attached as **PX-86** is a true and accurate copy of a March 8, 2018 presentation
titled [REDACTED] Bates numbered
MERCK-AT-0404785 – MERCK-AT-0404795 [REDACTED]
[REDACTED].

87. Attached as **PX-87** is a true and accurate copy of a July 10, 2018 Form 3542 for
U.S. Patent No. 9,717,852, Bates numbered SAMA01144991 – SAMA01144995 (“July 10, 2018
Form 3542 for ‘852 patent”).

88. Attached as **PX-88** is a true and accurate copy of a July 11, 2018 cover letter for
Form 3542 for U.S. Patent No. 9,717,852, Bates numbered SAMA01145000 (“July 11, 2018
cover ltr. for Form 3542 for ‘852 patent”).

89. Attached as **PX-89** is a true and accurate copy of a July 2018 [REDACTED]
[REDACTED], Bates numbered MERCK-AT-0404726 –
MERCK-AT-0404739 (“[REDACTED]”).

90. Attached as **PX-90** is a true and accurate copy of July 24, 2018 [REDACTED]
[REDACTED], Bates numbered MERCK-AT-0404740 – MERCK-AT-0404748 (“[REDACTED]
[REDACTED]”).

91. Attached as **PX-91** is a true and accurate copy of an August 22, 2018 [REDACTED]
[REDACTED], Bates numbered MERCK-AT-0404777 –
MERCK-AT-0404783 (“[REDACTED]”).

92. Attached as **PX-92** is a true and accurate copy of an August 30, 2018 Fierce Pharma article, “9 days for Gardasil 9 China hands out landmark nod with lightning speed,” <https://www.fiercepharma.com/pharma-asia/9-days-for-gardasil-9-china-hands-out-landmark-conditional-nod-lightning-speed>, Exhibit 0013 to the deposition of Janie Wang (“Aug. 30 2018 Fierce Pharma China gardasil approval”).

93. Attached as **PX-93** is a true and accurate copy of an October 15, 2018 [REDACTED], Bates numbered MERCK-AT-0000772 – MERCK-AT-0000776 (“[REDACTED]”).

94. Attached as **PX-94** is a true and accurate copy of an October 15, 2018 letter from Catherine Kohler, Director, Global Regulatory Affairs, Merck to FDA regarding Merck withdrawing NDA for pen, Bates numbered MERCK-AT-00000007 (“Oct. 15, 2018 withdrawal ltr”).

95. Attached as **PX-95** is a true and accurate copy of an October 22, 2018 letter from the FDA to Catherine Kohler, Director, Global Affairs, Merck regarding withdrawal of tentative approval, Bates numbered MERCK-AT-00000009 – MERCK-AT-00000010 (“Oct. 22, 2018 withdrawal ltr.”).

96. Attached as **PX-96** is a true and accurate copy of a December 2018 email chain [REDACTED] regarding Orange Book listing for U.S. Patent No. 9,717,852, SAMA03830229 – SAMA03830232 (“Dec. 2018 email chain re: ’852 patent”).

97. Attached as **PX-97** is a true and accurate copy of a February 2019 [REDACTED]
[REDACTED] Bates numbered

MERCK-AT-0003074 – MERCK-AT-0003085, Exhibit 0012 to the deposition of Janie Wang



98. Attached as **PX-98** is a true and accurate copy of a House of Representatives Report concerning the Orange Book Transparency Act of 2019, H.R. Rep. No. 116-47 (2019).

99. Attached as **PX-99** is a true and accurate copy of a November 19, 2019 Joint Statement of Uncontested Facts, *Sanofi-Aventis U.S. LLC, et al. v. Mylan GmbH, et al.*, 17-cv-09105, Docket No. 525-1, Bates Numbered SAMA03641388 – SAMA03641403 at Paragraph 21 (“*Sanofi v. Mylan* Joint Statement”).

100. Attached as **PX-100** is a true and accurate copy of an August 26, 2020 comment by Civica Inc. on Docket No. FDA-2020-N-1127, Bates Numbered SAMA03024737 – SAMA03024742 (“Aug. 26, 2020 Civica Comment on FDA-2020-N-1127”).

101. Attached as **PX-101** is a true and accurate copy of an August 31, 2020 comment by Apotex Inc. on Docket No. FDA-2020-N-1127, Bates Numbered SAMA03024857 – SAMA03024865 (“Aug. 31, 2020 Apotex Comment on FDA-2020-N-1127”).

102. Attached as **PX-102** is a true and accurate copy of Sanofi-Aventis U.S. LLC’s Responses and Objections to Direct Purchaser Class Plaintiffs’ First Set of Interrogatories to Defendants dated September 13, 2021 (“Sept. 13, 2021 Sanofi Interrog. Resp.”).

103. Attached as **PX-103** is a true and accurate copy of excerpts from the transcript of the March 29, 2022 deposition of Janie Wang (“Wang Dep.”).

104. Attached as **PX-104** is a true and accurate copy of the May 31, 2024 Expert Report of Nicolas P. Godici with Exhibits (“May 31, 2024 Godici Rep.”), excluding copies of attached patents. Purchasers removed copies of patents in Exhibit D to the May 31, 2024 Godici

Rep. that appear in the record at PX-17, PX-24, PX-27, PX-34, PX-43, PX-45, PX-47, PX-50, PX-58, PX-62, PX-65, PX-66, PX-69, PX-70, PX-73, PX-75, PX-78, PX-79, and PX-82.

105. Attached as **PX-105** is a true and accurate copy of the May 31, 2024 Expert Report of Gregory J. Glover, MD, JD (“May 31, 2024 Glover Rep.”).

106. Attached as **PX-106** is a true and accurate copy of the May 31, 2024 Expert Report of Robert Lechich (“May 31, 2024 Lechich Rep.”).

107. Attached as **PX-107** is a true and accurate copy of the May 31, 2024 Expert Report of Todd Clark (“May 31, 2024 Clark Rep.”).

108. Attached as **PX-108** is a true and accurate copy of the May 31, 2024 Opening Expert Report of Roger Williams, M.D. (“May 31, 2024 Williams Opening Rep.”).

109. Attached as **PX-109** is a true and accurate copy of the May 31, 2024 Expert Report of Guy Donatiello (“May 31, 2024 Donatiello Rep.”), excluding copies of attached patents. Purchasers removed copies of patents in Attachment D to the May 31, 2024 Donatiello Rep. that appear in the record at PX-3, PX-17, PX-24, PX-27, PX-34, PX-43, PX-47, PX-50, PX-58, PX-62, PX-65, PX-66, PX-69, PX-70, PX-73, PX-75.

110. Attached as **PX-110** is a true and accurate copy of the May 31, 2024 Expert Report of Keith O. Webber, Ph.D. (“May 31, 2024 Webber Rep.”).

111. Attached as **PX-111** is a true and accurate copy of the August 9, 2024 Expert Report of Roger Williams, M.D. in Opposition to the Report of Dr. Keith Webber (“Aug. 9, 2024 Williams Opp’n Rep. re Webber”).

112. Attached as **PX-112** is a true and accurate copy of the August 9, 2024 Expert Report of Roger Williams, M.D. in Opposition to the Report of Todd Clark (“Aug. 9, 2024 Williams Opp’n Rep. re Clark”).

113. Attached as **PX-113** is a true and accurate copy of the August 9, 2024 Opposition Expert Report of Mark Robbins, Ph.D., J.D. responding to the Expert Report of Todd Clark and Robert Lechich (“Aug. 9, 2024 Robbins Rebuttal Rep.”).

114. Attached as **PX-114** is a true and accurate copy of the August 9, 2024 Opposition Expert Report of Nicholas Davies responding to the Expert Report of Todd Clark and the Expert Report of Robert Lechich (“Aug. 9, 2024 Davies Rebuttal Rep.”).

115. Attached as **PX-115** is a true and accurate copy of the August 9, 2024 Opposition Report of Gregory J. Glover, MD, JD (“Aug. 9, 2024 Glover Opp’n Rep.”).

116. Attached as **PX-116** is a true and accurate copy of the August 9, 2024 Opposition Report of Nicholas Godici (“Aug. 9, 2024 Godici Opp’n Rep.”).

117. Attached as **PX-117** is a true and accurate copy of the August 9, 2024 Responsive Expert Report of Guy Donatiello (“Aug. 9, 2024 Donatiello Resp. Rep.”).

118. Attached as **PX-118** is a true and accurate copy of the August 9, 2024 Expert Report of David Kessler, M.D. (“Aug. 9, 2024 Kessler Rep.”).

119. Attached as **PX-119** is a true and accurate copy of the September 13, 2024 Rebuttal Expert Report of Keith Webber, Ph.D., responding to the Reports of Dr. Roger Lea Williams and Dr. Gregory Glover (“Sept. 13, 2024 Webber Rebuttal Rep.”).

120. Attached as **PX-120** is a true and accurate copy of the September 13, 2024 Rebuttal Expert Report of Robert Lechich responding to the Opposition Expert Report of Nicholas Davies and the Opposition Expert Report of Mark Robbins, Ph.D. (“Sept. 13, 2024 Lechich Rebuttal Rep.”).

121. Attached as **PX-121** is a true and accurate copy of the September 13, 2024 Rebuttal Expert Report of Roger Williams, M.D. responding to the Reports of Guy Donatiello and Dr. David Kessler (“Sept. 13, 2024 Williams Rebuttal Rep.”).

122. Attached as **PX-122** is a true and accurate copy of the September 13, 2024 Rebuttal Report of Nicholas Godici (“Sept. 13, 2024 Godici Rebuttal Rep.”).

123. Attached as **PX-123** is a true and accurate copy of the September 13, 2024 Rebuttal Report of Gregory J. Glover, MD, JD (“Sept. 13, 2024 Glover Rebuttal Rep.”).

124. Attached as **PX-124** is a true and accurate copy of the September 13, 2024 Reply Expert Report of Guy Donatiello (“Sept. 13, 2024 Donatiello Rep.”).

125. Attached as **PX-125** is a true and accurate copy of the September 13, 2024 Rebuttal Expert Report of Robert Lechich (“Sept. 13, 2024 Lechich Rep.”).

126. Attached as **PX-126** is a true and accurate copy of the September 13, 2024 Rebuttal Expert Report of Todd Clark, MBA, MS (“Sept. 13, 2024 Clark Rep.”).

127. Attached as **PX-127** is a true and accurate copy of excerpts from the transcript of the September 24, 2024 deposition of Nicholas Godici (“Godici Dep.”).

128. Attached as **PX-128** is a true and accurate copy of excerpts from the transcript of the October 2, 2024 deposition of Mark Robbins, Ph.D., J.D. (“Robbins Dep.”).

129. Attached as **PX-129** is a true and accurate copy of excerpts from the transcript of the October 8, 2024 deposition of Nicholas Davies (“Davies Dep.”).

130. Attached as **PX-130** is a true and accurate copy of the January 17, 2025 Supplemental Expert Report of Roger Williams, M.D. responding to the Expert Report of William Schultz, J.D., the Reply Expert Report of Guy Donatiello, and the Rebuttal Expert Report of Dr. Keith Webber (“Jan. 17, 2025 Williams Supp’l Rep.”).

131. Attached as **PX-131** is a true and accurate copy of the January 17, 2025 Supplemental Report of Gregory J. Glover, MD, JD (“Jan. 17 2025 Glover Supp’l Rep.”).

132. Attached as **PX-132** is a table setting out citations to the reports of Gregory J. Glover, Roger Williams, and Nicholas Godici that, in Purchasers’ view, contradict the First Circuit Court of Appeals decision in this case (“contradictions table”).

133. Attached as **PX-133** is a timeline of events including FDA submissions and approvals, patent submissions, patent expiry dates, and litigation events (“timeline”). Purchasers provide this to help orient the Court to the record before it.

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I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: March 7, 2025

/s/ Kristen A. Johnson
Kristen A. Johnson

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on March 7, 2025.

Dated: March 7, 2025

/s/ Kristen A. Johnson
Kristen A. Johnson